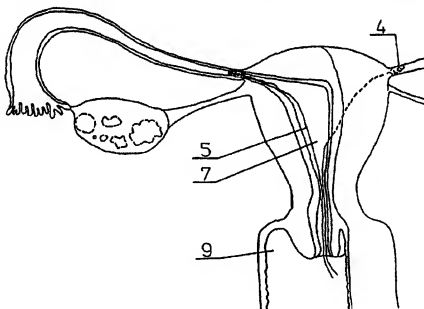




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<p>(21) International Application Number: PCT/CZ93/00013 (22) International Filing Date: 23 April 1993 (23.04.93) (71)(72) Applicants and Inventors: BABINEC, Bohdan [CZ/CZ]; Veltruská 19/536, 190 00 Praha 9 (CZ), UZEL, Radim [CZ/CZ]; Havlíčkova 1111, 180 00 Praha 8 (CZ). (74) Agent: PATENTSERVIS PRAHA; Jivenská 1273, 140 00 Praha 4 (CZ).</p>	<p>(81) Designated States: AU, BB, BG, BR, BY, CA, FI, HU, JP, KP, KR, LK, MC, MN, MW, NO, NZ, PL, RO, RU, SD, UA, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published With international search report.</p>	

(54) Title: METHOD, DEVICE AND APPARATUS FOR REVERSIBLE CONTRACEPTIVE STERILIZATION



(57) Abstract

A method of the reversible contraceptive sterilization where a blocking device is inserted into the fallopian tubes, that closes the passage through the fallopian tube and is left there for the desired sterilization time, and an apparatus to carry out this method where a blocking body (4) is placed in a flexible catheter (1) in front of the flexible mandrel (3) inserted in the flexible catheter (1) and a device to carry out the method according to invention, formed by the blocking body (4) provided with the manipulation thread (5).

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Method, Device and Apparatus for Reversible Contraceptive Sterilization

Field of the Art

The invention realates to a method, device and apparatus for reversible contraceptive sterilization.

Prior Art

The sterilization technique that has been applied up to this time and methods how it was applied constituted in reality an irreversible sterilization method. This method consisted e.g. in a ligation of the fallopian tubes through the abdominal wall either by laparotomy or by laparoscopy. Apart from the necessity to perform this relatively serious surgical intervention in anesthesia, this method is disadvantageous mainly for its irreversibility as the woman is not able to conceive and be a true mother for ever. The same consequence has also if the sterilization is carried out by the diathermocoagulation of the fallopian tubes using a laparoscope. Again it is a relatively complicated operation in anesthesia which is expensive and potentially dangerous for the woman.

Also, some barrier methods of contraception are known that use a pessary of various design. Their substantial disadvantage is that the pessary is necessary to be inserted before each intercourse what substantially limits the possibility to apply this method. In addition to it, not every woman is

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able to learn how to insert a pessary reliably. A certain number of women also have allergy to the rubber material used to make a pessary. This allergy can also be observed in cases when the man uses a condom. This method of contraception is considered by the man as a complication and makes the woman dependant on man's behaviour in contraception.

Also, the intra-uterine contraceptive devices inserted into the uterine cavity by physicians are known to be used. But this method is not a reliable contraception in all cases as it is not one hundred percent effective. In addition to it, this method brings about dangerous side-effects, especially inflammations and bleedings.

Application of the hormonal drugs for the purpose of contraception requires a regular administration to guarantee the necessary effectiveness. In a number of cases it is necessary to take into account certain unwanted side effects and consequences that can often manifest only after a long time and that can effect detrimentally on woman health.

Therefore, it can be concluded that the existing methods and means to carry out contraception or sterilization are always in some way disadvantageous. Either the irreversible sterilization is caused that prevents conception for ever, and can be a difficult and serious operation at the same time as it causes permanent blocking of the fallopian tubes, or the applied contraception method brings about a possibility of complications and side-effects. Also, many contraceptive methods are not one hundred percent effective.

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Summary of the Invention

The above mentioned drawbacks of the already known methods are nearly completely eliminated if the method, device and apparatus for reversible contraceptive sterilization according to the invention are used.

The method according to the invention consists in inserting a device according to the invention into each fallopian tube using preferably the apparatus according to the invention. The device closes the fallopian tube and is left there for the desired selected sterilization time.

The device consists of a blocking body provided with a manipulation thread.

In the application of the method according to the invention it is preferable to insert the device by means of the apparatus for reversible contraceptive sterilization according to the invention. This apparatus consists of a flexible catheter with a flexible mandren inserted into it. The above mentioned device is inserted into the flexible catheter in front of the flexible mandren and is inserted by the apparatus into one fallopian tube and deposited there. The method is then repeated for the other fallopian tube using another piece of the device.

The method of the reversible contraceptive sterilization according to the invention makes possible to sterilize by a simple operation. The sterility lasts for the desired time that can be even very long, in reality unlimited, but it is terminable at any time.

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The device for the reversible contraceptive sterilization is inert when introduced into an organism, causes no side-effects and if applied in both fallopian tubes the sterilization is reliable to one hundred percent.

The apparatus for the reversible contraceptive sterilization according to the invention permits a simple, quick and undemanding sterilization.

Brief Description of the Drawings

The invention is further illustrated by means of the accompanied drawings where the Figure 1 shows the method according to the invention in its first phase, the Figure 2 shows the next phase, the Figure 3 shows the device inserted by the method according to the invention, the Figure 4 shows section through the apparatus used to carry out the method according to the invention and the Figure 5 shows a detailed enlarged section through the device used in the application of the method according to the invention.

Preferred Embodiment of the Invention

The method according to the invention is carried out according to the Figures 1, 2 and 3 using the apparatus according to the Figure 4 and the device according to the Figure 5.

A flexible catheter 1 is used with a flexible mandren 2 running through its axial opening 2. The maximal external diameter of the flexible catheter 1 has to correspond to its possibility to be inserted into the orifice of the fallopian

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tube. The internal diameter of the flexible catheter 1 has to be such as to make possible to deposit the blocking body 4 in it (Figure 4, 5) at least at its end.

The blocking body 4 has preferably the shape of a short rod or cylinder with rounded tips. The manipulation thread 5 is fastened in the blocking body 4 and led out of it. The manipulation thread 5, which is preferably made from Mersilk, is fastened in the blocking body 4 for example so that it is provided with knots 6 by which it is fastened in the blocking body 4 during its moulding, e.g. by casting or injection moulding into a mould with the inserted thread 5. The manipulation thread 5 can be fixed also by other methods, e.g. so that its cross-section is increased during the blocking body 4 production. The blocking body 4 is preferably made from hydrophile swellable gel, but another material can also be used if it is indifferent to the organism.

The method according to the invention is carried out so that using a not shown hysteroscope inserted into the uterine cavity 7 the flexible catheter 1 with the blocking body 4 deposited in its axial cavity 2 at the end of the flexible mandren 3 is inserted into the orifice of the fallopian tube 8. When this flexible catheter 1 has been inserted through the vagina 9 and the uterine cavity 7 into the fallopian tube 8 orifice (Fig. 1) you start to pull the flexible catheter 1 out and at the same time you hold the blocking body 4 by the flexible mandren 3 in its place, resp. you push it by the mandren 3 with some feeling into the fallopian tube 8 so that you do not feel any resistance. The blocking body 4 has to remain in the place to which it was

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transported.

Thereafter, the flexible catheter 1 is removed from the uterine cavity 7 and subsequently also the flexible mandren 3, respectively the removal of the flexible catheter 1 and the flexible mandren 3 is carried out subsequently after the flexible catheter 1 has been pulled out of the fallopian tube 8 and the blocking body 4 in simultaneously held in its place. Thereafter, the flexible mandren 3 can be pulled out together with the partially pulled out flexible catheter 1. Within a relatively short time, about one day, the blocking body 4 from a hydrophilic swelling gel swells so that it completely closes the passage to the fallopian tube 8 as it comes into contact with the fallopian tube 8 wall.

The same method is applied also to the other fallopian tube 8 if it is functional. Thereafter, the manipulation thread 5 is shortened to the necessary length.

The blocking body 4 remains in the fallopian tube 8 for the desired time and reliably prevents the passage of spermatozoons to an ovum as it closes the passage through the fallopian tube 8.

Correct introduction of the blocking body 4 can be checked by X-raying or by sonography if the blocking body 4 contains an admixture of a detectable compound, e.g. of baryum sulphate.

If it is decided to terminate the sterilization to restore fertility the blocking body 4 is pulled out by pulling on

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the manipulation thread 5. The same is carried out also in the other fallopian tube 8 and the other blocking body 4 is also pulled out.

The commercial use of this invention will be constituted by any production of the apparatus and/or the device for the purpose to use them in carrying out the invented method.

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C l a i m s

1. A method of the reversible contraceptive sterilization characterized in that the blocking body that closes the passage through the fallopian tube is inserted there and left there for the decided sterilization time.
2. The method according to claim 1, characterized in that the inserted blocking body is removed from the fallopian tube to restore fertility.
3. The method according to claim 1, characterized in that the blocking body dilates spontaneously after insertion into the fallopian tube and closes the passage through the fallopian tube.
4. The method according to claim 1, characterized in that after insertion of the blocking body made with admixture of a sonographically or by X-rays detectable compound into the fallopian tube the insertion is checked by X-rays or sonographically.
5. The method according to claim 1, characterized in that the blocking body from hydrophilic swelling gel is inserted into the fallopian tube.
6. The method according to claim 1, characterized in that after insertion of a hysteroscope the flexible cathetre with the blocking body is inserted into the orifice of the fallopian tube, the blocking body is pushed and/or hold in the fallopian tube by the flexible mandren and when the flexible catheter and flexible mandren are

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pulled out the blocking body is left in the fallopian tube and by swelling closes the passage through it.

7. An apparatus for reversible contraceptive sterilization to be used in carrying out the method according to claim 1, characterized in that the blocking body (4) is deposited in the flexible catheter (1) in front of the flexible mandren (3) introduced into the flexible catheter (1).
8. The apparatus according to claim 7, characterized in that the blocking body (4) is deposited in the end of the axial opening (2) of the flexible catheter (1).
9. A device for the reversible contraceptive sterilization determined to carry out the method according to claim 1, characterized in that it is formed by the blocking body (4) provided with the manipulation thread (5).
10. The device according to claim 9, characterized in that the manipulation thread (5) is fixed in the blocking body (4) and led out of it.
11. The device according to claim 10, characterized in that the manipulation thread (5) is fixed in the blocking body (4) by knots (6) made on it.
12. The device according to claim 10, characterized in that the manipulation thread (5) is fixed in the blocking body (4) by its increased cross-section.

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13. The device according to claim 9, characterized in that the blocking body (4) is made as a rod from hydrophile swellable gel.
14. The device according to claim 9, characterized in that the blocking body (4) is made as a cylinder from hydrophile swellable gel.
15. The device according to claim 9, characterized in that the blocking body (4) is provided with a sonographically or by X-rays detectable compound.

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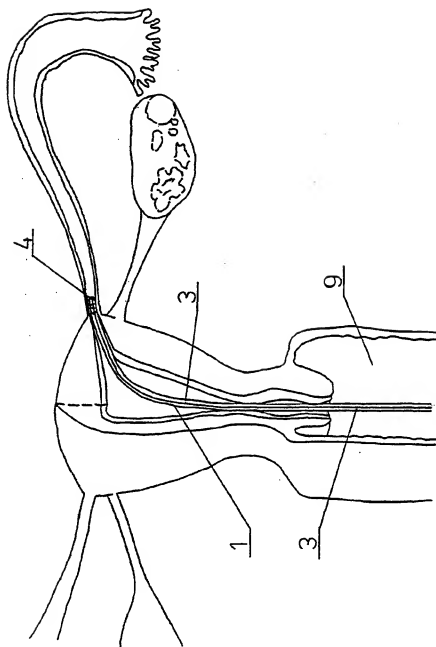


Fig. 1

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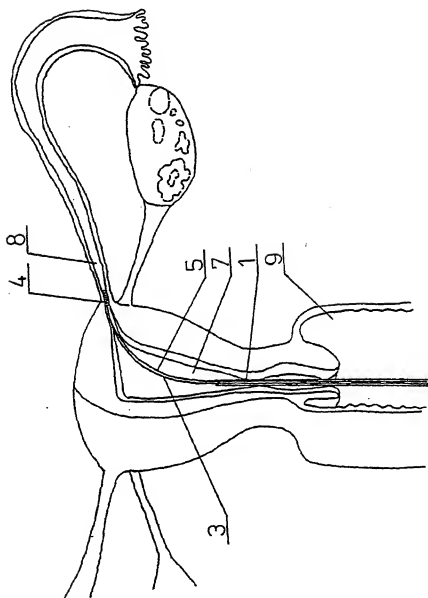


Fig. 2

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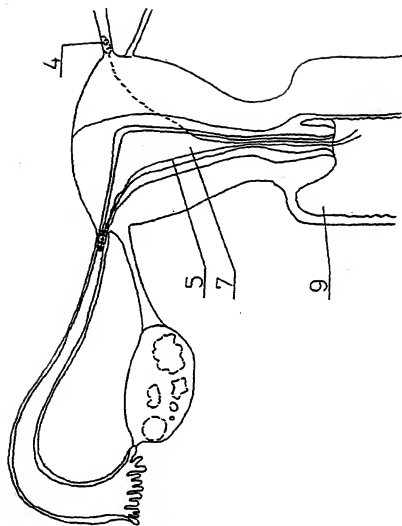


Fig. 3

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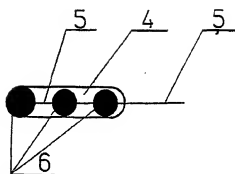


Fig. 4



Fig. 5

INTERNATIONAL SEARCH REPORT

 Inter- national Application No
 PCT/CZ 93/00013

 A. CLASSIFICATION OF SUBJECT MATTER
 IPC 5 A61B17/12 A61F6/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 5 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,83 00011 (MEDLINE) 6 January 1983	7-10,13, 14
Y	see the whole document, ----	11,12
Y	WO,A,91 07934 (METALLICOM) 13 June 1991 see page 5, line 27 - page 6, line 4; figures 5-8 ----	11,12
X	CH,A,638 393 (MEDLINE) 30 September 1983 see abstract; figures ----	9,10, 13-15
X	WO,A,81 01515 (MEDLINE) 11 June 1981 see the whole document ----	9,10,12, 13,15
A	EP,A,0 084 960 (RANGASWAMY) 3 August 1983 see page 3, line 4 - line 7; figure 3 -----	11

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

10 January 1994

Date of mailing of the international search report

14. 01. 94

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International application No.

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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-6
because they relate to subject matter not required to be searched by this Authority, namely:
Method for treatment of the human body by surgery.
Please see Rule 39.1 (iv).
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

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4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

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- ☐ The additional search fees were accompanied by the applicant's protest.
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INTERNATIONAL SEARCH REPORT

Information on patent family members.

Int. Prel. Application No.

PCT/CZ 93/00013

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		EP-A- 0094390	23-11-83
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		US-A- 4568326	04-02-86